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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,899	06/27/2003	Lisa M. Donnelly	022956-0218	7787

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NUTTER MCCLENNEN & FISH LLP
WORLD TRADE CENTER WEST
155 SEAPORT BOULEVARD
BOSTON, MA 02210-2604

EXAMINER

BLANCO, JAVIER G

ART UNIT	PAPER NUMBER
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3738

MAIL DATE	DELIVERY MODE
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05/04/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/608,899

Applicant(s)

DONNELLY ET AL.

Examiner

Javier G. Blanco

Art Unit

3738

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 23 April 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

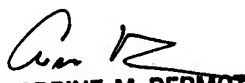
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 1-17, 20, and 21.
Claim(s) withdrawn from consideration: _____.

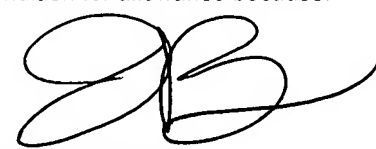
AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
13. ☒ Other: See Continuation Sheet.


CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700


Javier G. Blanco
April 27, 2007

Continuation of 13. Other:

1. With regards to the 102(b) rejection based on Bolton (US 5,906,632 A), Applicants' arguments filed April 23, 2007 have been fully considered but they are not persuasive.

Bolton clearly discloses the subject matter of a graft fixation device comprising:

(i) A bioabsorbable (see column 4, lines 22-27) radially expandable sheath (anchor 20) having a bullet-shaped (see column 7, lines 1-4) slot-free distal tip (tip/point 222) with at least two sidewalls (212, 213) extending proximally therefrom and defining a central lumen (central lumen defined between bore 220 and bore 221), each sidewall having a substantially concave outer surface (grooves 210) capable of seating (see column 4, lines 8-15) a graft member (80, 82), and each sidewall being at least partially separated by a longitudinally oriented opening (groove 218) extending from a proximal end (223) along a substantial length of each sidewall and terminating at a position just proximal to the distal tip (i.e., it does NOT open/terminate in distal tip 222, therefore it does not create a slot/slit therein); and

(ii) A bioabsorbable (see column 4, lines 42-44) sheath expander (screw 40) capable of being disposed in the central lumen of the radially expandable sheath, and CAPABLE OF flexing/deforming the concave outer surface of the sidewalls toward a circular geometry (see Figures 6A-6F; see column 4, lines 45-61). Alternatively, the "circular geometry" could be broadly interpreted as the circular geometry of the bone tunnel/bore (i.e., the concave outer surface of the sidewall will be deformed in the direction of the circular geometry of the bone tunnel/bore).

2. With regards to the 102(e) rejection as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Justin et al. (US 6,887,271 B2), Applicants' arguments filed April 23, 2007 have been fully considered but they are not persuasive.

Justin et al. clearly disclose the subject matter of a graft fixation device comprising:

(i) A bioabsorbable (see column 6, lines 34-38) radially expandable sheath (fixation members 20, 50) having a bullet-shaped slot-free distal tip (tip/point 112) with at least two sidewalls (see Figures 2 and 6) extending proximally therefrom and defining a central lumen (eyelet 24 and/or opening 22, 55), each sidewall having a substantially concave outer surface (grooves 23) capable of seating (see column 4, lines 15-20; column 5, lines 3-8; column 7, lines 48-54) a graft member (200), and each sidewall being at least partially separated by a longitudinally oriented opening (slots 24, 360, 370) extending from a proximal end along a substantial length of each sidewall and terminating at a position just proximal to the distal tip; and

(ii) A bioabsorbable (see column 6, lines 34-38) sheath expander (expansion plug 21, 52, 310) capable of being disposed in the central lumen of the radially expandable sheath, and CAPABLE OF flexing/deforming the concave outer surface of the sidewalls toward a circular geometry (see column 4, lines 15-20; column 5, lines 3-8; column 7, lines 48-54). Alternatively, the "circular geometry" could be broadly interpreted as the circular geometry of the bone tunnel/bore (i.e., the concave outer surface of the sidewall will be deformed in the direction of the circular geometry of the bone tunnel/bore).

3. With regards to the 103(a) rejection based on Jacobs et al. (WO 02/32345 A2; cited in Applicants' IDS), Applicants' arguments filed April 23, 2007 have been fully considered but they are not persuasive.

a. Regarding claim 1, the Applicants argue that Jacobs et al. does not disclose newly added (functional) limitation: "configured to deform the concave outer surface of the sidewalls toward a circular geometry". The Examiner respectfully disagrees. The "circular geometry" could be broadly interpreted as the circular geometry of the bone tunnel/bore (i.e., the concave outer surface of the sidewall is capable of being deformed/flexed in the direction of the circular geometry of the bone tunnel/bore). Also, the material of Jacobs et al.'s sheath/sleeve is the same as Applicants' sheath/sleeve, and intended for the same purpose (anchoring a ligament/tendon/graft). Expansion of the bioabsorbable radially expandable sheath (i.e., by introduction of an expander) will provide at the least some level of deformation of the concave surface towards a "circular geometry".

b. Regarding claim 11, it will be inherent that a range of sheath & expander pairs will be available to the surgeon in the operating room so as to accommodate variations in drilled hole/tunnel sizes. The invention may comprise a kit of expandable sheaths and expanders, wherein a properly dimensioned (i.e., depends on the particular bone tunnel diameter and/or length) sheath/sleeve will receive a correspondingly dimensioned sheath/sleeve expander..